

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 29D2257807	<b>(X3) Date Survey Completed</b> 05/25/2023
<b>Name of Provider or Supplier</b> Star Diagnostics	<b>Street Address, City, State</b> 215 E Warm Springs Rd Ste 108, Las Vegas, NV	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	This Statement of Deficiencies was created as a result of an on-site initial CLIA survey conducted at your facility on May 25, 2023. The findings and conclusions of any investigation by the Division of Public and Behavioral Health shall not be construed as prohibiting any criminal or civil investigations, actions or other claims for relief that may be available to any party under applicable federal, state, or local laws.
<b>D5807</b>	<p>TEST REPORT CFR(s): 493.1291(d)</p> <p>Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the laboratory quality assessment records for eight of 80 patients whose specimens were sent to reference laboratories in April 2023, and an interview with the general supervisor, the laboratory failed to ensure that the report issued by the laboratory included pertinent reference intervals and interpretive guidance for the Hemoglobin A1c test. Findings include: 1. A review of the final report issued by the laboratory for two of eight patients that the laboratory reviewed for quality assessment for April, 2023 revealed that the laboratory failed to include the reference interval and interpretive guidance present on the reference laboratory report for the Hemoglobin A1c test. 2. The finding was confirmed during an interview with the general supervisor on May 25, 2023 at approximately 10:45 AM. The laboratory sends approximately 960 patient specimens to reference laboratories annually.</p>
<b>D5817</b>	<p>TEST REPORT CFR(s): 493.1291(i)</p>

If a laboratory refers patient specimens for testing-- (i)(1) The referring laboratory must not revise results or information directly related to the interpretation of results provided by the testing laboratory; (i)(2) The referring laboratory may permit each testing laboratory to send the test result directly to the authorized person who initially requested the test. The referring laboratory must retain or be able to produce an exact duplicate of each testing laboratory's report; and (i)(3) The authorized person who orders a test must be notified by the referring laboratory of the name and address of each laboratory location where the test was performed.

This STANDARD is not met as evidenced by:

Based on a review of the laboratory quality assessment records for eight of 80 patients whose specimens were sent to reference laboratories in April 2023, and an interview with the general supervisor, the laboratory failed to ensure that the final reports issued by the laboratory included the correct reference intervals present on the reference laboratory reports. Findings include: 1. A review of eight final reports issued by the laboratory during April, 2023 revealed that the reference intervals on the final laboratory report issued to the providers did not match the reference intervals on the reports from the reference laboratories. 2. Three of eight reports reviewed revealed that the patient specimens were sent to American Specialty Laboratory (CLIA ID 29D2102809). One of three final reports from the laboratory had discrepant reference ranges from those of the reference laboratory for carbon dioxide (CO2) and glucose. One of three final reports from the laboratory had a discrepant reference range from that of the reference laboratory for carbon dioxide (CO2), glucose, and Thyroid Stimulating Hormone (TSH). One of three final reports from the laboratory had a discrepant reference range from that of the reference laboratory for creatinine. 3. Five of eight reports reviewed revealed that the patient specimens were sent to Clinical Pathology Laboratories (CLIA ID 29D1075255). Two of five final reports from the laboratory had discrepant reference ranges for the Basic Metabolic Panel, Complete Blood Count (CBC), and magnesium. One of five final reports from the laboratory had discrepant reference ranges for the Basic Metabolic Panel, Complete Blood Count (CBC), magnesium, and Thyroid Stimulating Hormone (TSH). One of five final reports from the laboratory had discrepant reference ranges for the Basic Metabolic Panel and Free T4. One of five final reports from the laboratory had a discrepant reference range for the Prottime. 4. The findings were confirmed during an interview with the general supervisor on May 25, 2023 at approximately 10:45 AM. The laboratory sends approximately 960 patient specimens to reference laboratories annually.

**D5891**

**POSTANALYTIC SYSTEMS QUALITY ASSESSMENT**  
CFR(s): 493.1299(a)

The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291.

This STANDARD is not met as evidenced by:

Based on a review of the laboratory quality assessment records for April, 2023, a review of the director approved policy entitled, "Quality Management Plan," and an interview with the general supervisor, the laboratory failed to ensure that a specific step by step policy and procedure was established and followed for an ongoing mechanism to monitor, assess and correct problems identified in the postanalytic

systems. Findings include: 1. A review of the quality assessment records for April, 2023 revealed that the laboratory failed to detect and correct the reference ranges released on the final reports issued by the laboratory that were discrepant from the reference laboratory ranges for the patient specimens sent out for testing. 2. A review of the director approved policy entitled, "Quality Management Plan" revealed that there were no specific instructions or established criteria for review in order to detect and correct problems or errors when they occurred. 3. The findings were confirmed during an interview with the general supervisor conducted on May 25, 2023 at approximately 11:15 AM. The laboratory sends approximately 960 patient specimens to reference laboratories annually.